

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/107 A61K31/337 A61K38/13

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data, BIOSIS, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	EP 1 340 497 A (NOVAGALI SAS ;YISSUM RES DEV CO (IL)) 3 September 2003 (2003-09-03) paragraph '0025! paragraph '0048! claims examples	1-21
A	WO 02/43765 A (TRANSFORM PHARMACEUTICALS INC ;CHEN HONGMING (US)) 6 June 2002 (2002-06-06) page 4, line 31 - page 5, line 1 page 14, line 4 - line 21 See Formulations G,H,I,J,K ----- -/--	1-21

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

26 October 2004

Date of mailing of the international search report

04/11/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Giménez Miralles, J

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 509 370 B1 (GORE ASHOK Y ET AL) 21 January 2003 (2003-01-21) column 3, line 8 - column 4, line 8 column 6, line 42 - line 48 examples -----	1-21
A	US 6 458 373 B1 (CONSTANTINIDES PANAYIOTIS P ET AL) 1 October 2002 (2002-10-01) column 3, line 45 - column 4, line 18 examples -----	1-21
A	WO 99/45918 A (NAPRO BIOTHERAPEUTICS INC) 16 September 1999 (1999-09-16) page 3, line 3 - line 32 examples 8,10,11 -----	1-21
A	US 2002/156124 A1 (MOROZOWICH WALTER ET AL) 24 October 2002 (2002-10-24) paragraph '0025! - paragraph '0030! paragraph '0033! - paragraph '0041! paragraph '0072! - paragraph '0079! -----	1-21
A	WO 95/11039 A (HEXAL PHARMA GMBH ;KLOKKERS KARIN (DE); FISCHER WILFRIED (DE)) 27 April 1995 (1995-04-27) example 3 -----	1-21
A	WO 00/78247 A (BAKER NORTON PHARMA) 28 December 2000 (2000-12-28) page 8, line 12 - page 9, line 6 page 10, line 18 - page 11, line 21 example 8 -----	1-21

INTERNATIONAL SEARCH REPORT

national application No.
PCT/IB2004/003077

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 21
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 21 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.: 1-21 in part
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Although claim 21 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box II.1

Claims Nos.: 21

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box II.2

Claims Nos.: 1-21 in part

Present claims 1-21 relate to an extremely large number of possible pharmaceutical compositions, namely all those comprising active agent(s) "which have low solubility in water or are water-insoluble" (claim 1).

Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compositions claimed, namely those wherein the active agent is a taxoid (particularly paclitaxel) within the meaning of claims 6 and 7. Compositions comprising other active agents, even if speculatively mentioned in a long list (cf. claim 4), cannot be considered to be sufficiently disclosed in the description, because it is not made credible or shown that the relevant technical problem is effectively solved in the same way for all of the active agents listed in claim 4.

In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the compositions as claimed in claim 1 in combination with claims 6 and 7.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
EP 1340497	A	03-09-2003	EP	1340497 A1	03-09-2003
			WO	03074027 A2	12-09-2003
WO 0243765	A	06-06-2002	AU	3928202 A	11-06-2002
			EP	1337273 A2	27-08-2003
			WO	0243765 A2	06-06-2002
US 6509370	B1	21-01-2003	US	2002103254 A1	01-08-2002
			US	6319943 B1	20-11-2001
			US	6136846 A	24-10-2000
			US	2003191179 A1	09-10-2003
			AU	7490200 A	08-05-2001
			CA	2388613 A1	03-05-2001
			CN	1382038 T	27-11-2002
			EP	1225872 A1	31-07-2002
			JP	2003512416 T	02-04-2003
			WO	0130319 A1	03-05-2001
US 6458373	B1	01-10-2002	CA	2276730 A1	16-07-1998
			EP	0981328 A1	01-03-2000
			IN	183539 A1	05-02-2000
			JP	2001508445 T	26-06-2001
			TW	579297 B	11-03-2004
			WO	9830205 A1	16-07-1998
			US	2003027858 A1	06-02-2003
			US	2003104015 A1	05-06-2003
			US	2003109575 A1	12-06-2003
			US	2003105156 A1	05-06-2003
			US	2003087953 A1	08-05-2003
			US	2003087954 A1	08-05-2003
			US	2003147959 A1	07-08-2003
			US	2003170279 A1	11-09-2003
			US	6660286 B1	09-12-2003
			US	6667048 B1	23-12-2003
			US	2004202712 A1	14-10-2004
			AU	5731498 A	03-08-1998
			ZA	9800098 A	08-07-1998
WO 9945918	A	16-09-1999	AU	762926 B2	10-07-2003
			AU	2902299 A	27-09-1999
			BR	9904856 A	18-07-2000
			CA	2288240 A1	16-09-1999
			CN	1255852 T	07-06-2000
			EP	0977562 A1	09-02-2000
			JP	2001524988 T	04-12-2001
			WO	9945918 A1	16-09-1999
			US	2001029264 A1	11-10-2001
			ZA	9901885 A	10-09-1999
US 2002156124	A1	24-10-2002	BR	0206580 A	16-12-2003
			CA	2434338 A1	25-07-2002
			CA	2434641 A1	22-08-2002
			CZ	20031844 A3	17-12-2003
			EP	1365812 A2	03-12-2003
			EP	1365759 A2	03-12-2003
			JP	2004520359 T	08-07-2004
			JP	2004520398 T	08-07-2004
			NO	20033244 A	17-09-2003

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002156124 A1		WO 02064132 A2	22-08-2002
		WO 02056878 A2	25-07-2002
		US 2003045563 A1	06-03-2003
WO 9511039 A	27-04-1995	DE 10199039 I1	22-11-2001
		DE 59409377 D1	29-06-2000
		WO 9511039 A1	27-04-1995
		EP 0724452 A1	07-08-1996
		ES 2148345 T3	16-10-2000
		JP 9504012 T	22-04-1997
		US 6022852 A	08-02-2000
WO 0078247 A	28-12-2000	WO 0078247 A1	28-12-2000
		AU 774060 B2	17-06-2004
		AU 4695599 A	09-01-2001
		BR 9917403 A	09-07-2002
		CA 2371924 A1	28-12-2000
		CZ 20014589 A3	17-07-2002
		EP 1221908 A1	17-07-2002
		HU 0300836 A2	28-08-2003
		JP 2003502349 T	21-01-2003
		NO 20016198 A	05-02-2002
		NZ 516279 A	25-06-2004
		SK 18782001 A3	10-09-2002